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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,841	05/22/2001	Karla Kirkegaard	STAN-193	8970
24353	7590	02/15/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/863,841

Applicant(s)

KIRKEGAARD ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 4-12 and 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Amendment filed 11/30/2004 is acknowledged. Claims 1-24 are pending. Claims 4-12, 17-24 remain withdrawn from consideration.

#### ***Claim Rejections - 35 USC 112, second paragraph.***

2. Claim 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "surface identified by residues at corresponding positions" is indefinite as the term "corresponding positions" is not defined and thus the surface to which the pharmacophore is supposed to bind is also undefined.

#### Response to arguments

Applicant refers to definition of "corresponding positions" in specification which defines such position as same position "in the sequence of conserved binding surface of different viral polymerases". However neither "conserved binding surface of different viral polymerases" nor corresponding positions in different polymerases are identified. Contrary, specification teaches that "while showing many similarities to other polymerases, the structure of the poliovirus RNA-dependent RNA polymerase showed many surprising and exciting features".

Therefore, it is not clear, either what residues are "at corresponding positions", or what constitutes "surface identified by residues at corresponding positions".

***Claim Rejections - 35 USC 112, first paragraph.***

3. Claims 1-3, 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons of record and further in view of the following.

In response to the rejection, applicant, first, describes the structure regions of interface I . This is not relevant to the disclosure requirement in which the applicant must demonstrate possession of the claimed scope at the time of filing.

Further, applicant refers to the peptide of example 10 as providing sufficient support for the claimed subject matter. However, said peptide is designed to mimic one (of several) helical regions of the interface, there is no evidence that it satisfies the characteristics required by claim 1. There is no evidence that said polypeptide belongs to the genus as claimed, i.e, that it does bind to the specified residues 342 and 349 of RNA-polymerase.

Specification does not have a single example of a peptide within the scope of the invention as claimed, i.e. of a pharmacophore that selectively binds to surface of interface I, (more specifically selectively binds to the surface defined by residues 342 and 349 of RNA-polymerase) and thus does not provide even a single species in support of a potentially broad genus of different and nonexemplified products.

4. Claims 1-3, 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification is not enabling for making of the product as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The rejection is maintained for the reasons of record and further in view of the following.

Examiner agrees with applicant's argument that a pharmacophore should bind to the surface of the polymerase, rather than to any surface defined by location of such residues. However, the specification is still not enabling for making of the product as claimed, i.e., a making a pharmacophore capable of selective binding to a "binding surface" of RNA polymerase. The binding surfaces addressed in this invention are Interface I and Interface II of RNA-dependent RNA polymerases (see paragraph [0008]. The "surface" on Fig. 2 is not detailed enough to sufficiently enable making a pharmacophore that is capable of selective binding to a

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"binding surface" of RNA polymerase. The peptide SEQ ID No. 5 (Example 10), although demonstrated to disrupt RNA-polymerase functions, is not demonstrated to selectively bind to a "binding surface" of RNA polymerase; said peptide is designed to mimic one (of several) helical regions of the interface. Specification reviews known methods of drug modeling (pages 14-19); however, this description does not address the issue of undefined structure to which pharmacophore is supposed to bind. It is the Examiners position that with the insufficient guidance and working examples, one skilled in the art could not make the invention with the claimed breadth without an undue amount of experimentation.

***Claim Rejections - 35 USC 102 and 103***

5. Claims 1-3, 14-16 are rejected under 35 U.S.C. 102(b) as anticipated by Sergio et al. ( US Patent 6,492,423). The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that pharmacophores described in Sergio reference target "active sites" of RNA polymerases. However, as stated in the rejection, Sergio et al only speculate about potential mechanism of interaction ("may act by interfering with binding at the active site", "inventors hypothesize", etc) but does not specify the exact nature of interaction of diketoacids with RNA-dependent RNA-polymerases. On the other hand, the pharmacophores of the instant invention are

not limited to "binding", but, similarly to the referenced compounds, effect activity of RNA-polymerase (see claim 1 and specification, p. 9, bottom).

Reference of Lyle et al is noticed but it is not a prior art and is not a later publication of inventors.

The rejection is maintained.

6. Rejection of claim 13 under 35 U.S.C. 103(a) as obvious over Sergio et al. (US Patent 6,492,423) is maintained for the reasons of record. Applicant considers this rejection obviated by traverse of the rejection under 35 U.S.C. 102(b), above; however, the above rejection is maintained.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will


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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb